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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,414	05/10/2001	Gerald Horn	HORN006CIP	7675

24573 7590 10/02/2002

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EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/02/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/584,414

Applicant(s)

Horn

Examiner

Zohreh Fay

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit:

Claims 1-43 are presented for examination.

1. Claims 1-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain compounds, does not reasonably provide enablement for the broad phrase of “a compound characterized by its ability to disrupt endogenous compounds which stimulate dilator muscle of the eye” and “a first active compound characterized by its ability to reduce dilation of the human eye”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice instant invention without undue experimentation. Attention is directed to *In re Wanda*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex Parte Forman*, 230 USPQ 546 (Bdaps 1986) at 547 the court recited eight factors:

- 1) the amount of direction or guidance provided,
- 2) The presence or absence of working examples,
- 3) the nature of the invention,
- 4) the state of the art,
- 5) the relative skill of those in the art,
- 6) the predictability of the art
- 7) the breadth of the claims.

Art Unit:

Applicant set forth the criteria that defines “a compound characterized by its ability to disrupt endogenous compounds which stimulates dilator muscles of the eye” and a first active compound characterized by its ability to reduce dilation of a human eye”. Additionally applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. The pharmaceutical art is unpredictable requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all “compounds characterized by its ability to disrupt endogenous compounds which stimulate dilator muscles of the eye” and all “active compound characterized by its ability to reducedilation of a human eye”, necessitating an exhaustive search for the embodiment suitable to practice the claimed invention. Applicant fails to provide information sufficient to practice the claimed invention, absence undue experimentation.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102 (b) as being anticipated by Galin (U.S. Patent 4,443,441). Galin teaches the use of the claimed alpha adrenergic compound phentolamine as a miotic agent in a pharmaceutical formulation. The above reference makes clear that the claimed composition is old and well known.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41 and 42 are rejected under 35 U.S.C. 103 as being unpatentable over Dougherty (U.S.

Patent 4,515,295). Dougherty teaches the use of an eye drop dispenser for administering eye drops. See column 1, lines 12-20. The above reference differs from the claimed invention in the presence of an agent, which stimulates the dilation of the muscle of the eye and also the size of the inner surface barrel. It would have been obvious to a person skilled in the art to use an eye medication in an eye dropper in ophthalmic field. The determination of the inner surface of a barrel is considered to be within the skill of the artisan in the absence of evidence to the contrary. One skilled in the art would have been motivated to employ the teachings of the above reference since it relates to an eye dropper with a hollow barrel comprising two ends and a mean for dispensing the medication. To add a specific component to an eye dropper does not create a patentably distinct eye dropper. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 41 and 42 are properly rejected under 35 U.S.C. 103.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg.*

Art Unit:

Co., 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 29-36 and 41-42 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7-15 and 20-21 of copending Application No. 09/705,526. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Fay whose telephone number is (703) 308-4604.

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

